

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/553,683

Confirmation No.: 6497

Filed: 21 April 2000

For: SURGICAL TARGETING SYSTEM

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**Remarks**

The Final Office Action mailed 11 February 2004 has been received and reviewed. Claims 30, 32, 34, 35, 57, and 59 having been amended; claims 31, 33, 58, and 60 having been cancelled, and new claims 67-75 having been added, the pending claims are claims 28-30, 32, 34-57, 59, and 61-75, with claims 28 and 29 indicated by the Examiner as being allowable.

This response is being filed concurrently with a Request for Continued Examination. Entry and consideration of the amended and new claims are, therefore, respectfully requested.

Reconsideration and withdrawal of the rejections in view of the above amendments and the following comments are respectfully requested.

**Allowable Subject Matter**

Applicant thanks the Examiner for notification to the effect that claims 28 and 29 are allowable. Applicant, however, points out that on the Office Action Summary Sheet of the present Office Action, it is indicated that claims 28 and 29 are rejected.

**The 35 U.S.C. §103 Rejections**

The Examiner rejected claims 30-38, 41-43, 47-49, and 53-61 under 35 U.S.C. §103(a) as being unpatentable over Muller (U.S. Patent No. 4,899,762), in view of Krupnick (U.S. Patent No. 5,052,035). Applicant respectfully traverses this rejection.

At the outset, Applicant notes that claims 31, 33, 58 and 60 have been canceled, rendering their rejection moot.

Applicant submits that remaining claims 30, 32, 34-38, 41-43, 47-49, and 53-57, 59, and 61 are not *prima facie* obvious for at least the following reasons. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there

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must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

As amended, independent claims 30 and 57 recited surgical drapes that include "a plurality of uniquely labeled intersections" that are "in the interior of the radio-opaque pattern." None of the cited references disclose such a construction.

The labels of Muller are located only at the periphery of the drape. Nor does Krupnick disclose unique labels located within the interior of the pattern formed thereon. For example, in Figure 1 of both Muller and Krupnick, all of the labels are located at the perimeters of the radio-opaque patterns. Significantly, neither Muller or Krupnick teach or suggest that either individual intersections be labeled, or that labels are located within the interior of the radio-opaque pattern. Thus, the proposed combination of Muller and Krupnick fail to teach or suggest all the limitations of independent claims 30 and 57 and their respective dependent claims subject to this rejection as would be required for a proper *prima facie* case of obviousness.

With respect to independent claims 47 and 61, neither Muller or Krupnick teach or suggest that "every intersection of the plurality of intersections comprises one of the radio-opaque labels such that every intersection of the plurality of intersections comprises one of the labeled intersections of the plurality of labeled intersections" as is recited. Rather, the cited references teach patterns in which the labels are limited to the edges or perimeters of the patterns. As a result, labels are not found at every intersection as recited in independent claims 47 and 61 and dependent claims 48 and 49.

As for the comments related to "criticality" of the labeled intersections found on page 2 of the Office Action, Applicants note that, in fact, some potential advantages have been identified for including unique labels within the interior of the radio-opaque pattern on surgical drapes in the Specification. *See, e.g.*, p. 19, lines 11-29. As indicated, accurate identification of the surgical site may be facilitated by including labels at intersections within the interior of the pattern. Actual physical labels located at intersections within the interior of the pattern are not,

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therefore, "functional equivalents" to imaginary labels that do not physically exist, but that must, instead, be derived from labels at the edges of a pattern.

With respect to independent claim 53, Applicants note that neither Muller or Krupnick disclose or suggest (alone or in combination) a surgical drape that includes "a central cutout and a slit extending outward from the central cutout" as recited.

It is asserted that Krupnick discloses "a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31)." Applicant disagrees. First, the features disclosed by Krupnick are limited to die cut lines in the sheet, not a cutout in the sheet as recited in claim 53. Krupnick does not disclose that any material is removed by the die cutting. Rather, the corners at the die cut intersection must be raised to permit marking of the underlying surgical site. Second, Krupnick does not disclose a line extending outward from a cutout because no cutout itself is disclosed. As a result, Applicant respectfully submits that a proper *prima facie* case of obviousness has not been established with respect to claim 53 and its dependent claims subject to this rejection (54-56).

For at least the above reasons, Applicant respectfully submits that claims 30, 32, 34-38, 41-43, 47-49, and 53-57, 59, and 61 are not *prima facie* obvious over Muller in view of Krupnick. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

The Examiner rejected claims 39-40, 44-46, 50-52, and 62-66 under 35 U.S.C. § 103(a) as being unpatentable over Muller (U.S. Patent No. 4,899,762) in view of Krupnick (U.S. Patent No. 5,052,035), and Mosby (U.S. Patent No. 5,260,985). Applicant respectfully traverses this rejection.

Applicant submits that claims 39-40, 44-46, 50-52, and 62-66 are not *prima facie* obvious over Muller in view of Krupnick and Mosby for at least the reason that the combination of Muller, Krupnick and Mosby does not teach all of the features recited in those claims.

All of claims 39-40, 44-46, and 50-52 depend from one of the independent claims discussed above with respect to the rejection based on only Muller and Krupnick. The addition

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of Mosby does not address any of the deficiencies of Muller and Krupnick as applied to those independent claims. For that reason alone, Applicant respectfully submits that claims 39-40, 44-46, and 50-52 are patentable over the combination of Muller in view of Krupnick and Mosby.

With respect to dependent claim 50, Applicant further notes Mosby does not disclose or suggest "a slit extending outward from the central cutout" as recited in claim 49, from which claim 50 depends.

With respect to dependent claims 45, 46, 51, 52, Applicant notes that the combination of Muller in view of Krupnick and Mosby does not disclose or suggest "a cylindrical portion adapted to fit over a finger" as recited in claims 45 and 51. Nor does the combination of Muller in view of Krupnick and Mosby teach or suggest "a hemispherical end portion located at one end of the cylindrical portion" as recited in claims 46 and 52.

The rejection of claims 45, 46, 51 and 52 is premised on the assertion that the cited portions of Mosby teach "the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger." Office Action, page 4, lines 14-16. A careful review of Mosby (including the portions cited in support of this rejection), however, reveals that Mosby does not disclose or suggest that the adhesive sheet may be used on a finger. As a result, the rejection of claims 45, 46, 51, and 52 is not supported by the combination of Muller in view of Krupnick and Mosby.

With respect to independent method claims 62 & 64, Applicant submits that the combination of Muller in view of Krupnick and Mosby does not teach or suggest "a plurality of unique radio-opaque labels disposed over the surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections disposed over the surgical drape" as recited in each of these independent claims. One example of such an arrangement is depicted in, *e.g.*, Figure 1 of the present application.

In contrast, Muller and Krupnick both teach that labels are limited to the perimeter of the patterns formed on the sheets. For example, in Figure 1 of both Muller and Krupnick illustrate

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this point, *i.e.*, all of the labels are located at the perimeters of the radio-opaque patterns.

Significantly, neither Muller or Krupnick teach or suggest that individual intersections be labeled. Mosby does not teach any labels on the sheet material.

As a result, the combination of Muller in view of Krupnick and Mosby does not support a *prima facie* case of obviousness with respect to independent claims 62 and 64 or their respective independent claims 63, 65, and 66.

With respect to independent claim 62, Applicant notes that the combination of Muller in view of Krupnick and Mosby also do not teach or suggest "a central cutout and a slit extending outward from the central cutout" as recited in claim 62.

With respect to independent claim 64, the combination of Muller in view of Krupnick and Mosby does not teach or suggest "unrolling a cylindrical portion of the surgical drape onto an extremity, finger or other appendage of the patient" as recited. In fact, the Office Action is silent as to where these actions are taught in the cited references or how they are rendered obvious in view of the cited references.

In view of the above, Applicant respectfully submits that claims 39-40, 44-46, 50-52, and 62-66 are not *prima facie* obvious over Muller in view of Krupnick and Mosby. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

#### **New Claims 67-79**

Applicants respectfully submit new claims 67-75 to provide more comprehensive coverage of Applicant's invention. Applicant respectfully submits that new claims are patentable and request their entry and consideration.

#### **Summary**

It is respectfully submitted that the pending claims 28-30, 32, 34-57, 59, and 61-75 are in condition for allowance and notification to that effect is respectfully requested.

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The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14th day of June, 2004, at 5:05 p.m. (Central Time).

By: Rachel Gagliardi-Gibson Name: Rachel Gagliardi-Gibson